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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,046	09/26/2003	David M. Gravett	110129.430	8047

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/673,046	GRAVETT ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 2, 13-15, 20-54, 65-72, 90-93, 98, 99, 102, 114, 115, 118-147, 158-164, 182-192, 198-203 and 232-237* is/are pending in the application.

4a) Of the above claim(s) *15-20, 22-25, 28-33, 42-54, 65, 66, 70, 71, 90-93, 98, 99, 102, 114, 115, 118-147, 158-164, 182-192, 198-203 and 233-237* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,13,14,21,26,27,34-41,67-69,72 and 232* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/27/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of amendment to the claims and specification, remarks and request for extension of time, all filed 1/22/08. Claims 3-12, 16-19, 55-64, 73-89, 94-97, 100, 101, 103-113, 116, 117, 148-157, 165-181, 193-197 and 204-231 are canceled. New claims 232-237 are added. Claims 1, 2, 13-15, 20-26, 35, 41, 44, 48, 53, 54, 67, 72, 98, 102, 114, 115, 118-125, 131, 132, 139, 142, 146, 147, 159, 164, 189, 191 and 198 are amended. Claims 15-20, 22-25, 28-33, 42-54, 65, 66, 70, 71, 90-93, 98, 99, 102, 114, 115, 118-147, 158-164, 182-192, 198-203 and new claims 233- 237 are withdrawn from consideration. Claims 1, 2, 13, 14, 21, 26, 27, 34-41, 67-69, 72 and 232 are examined. Claims 234 and 235 depend from withdrawn claim 233 and are therefore withdrawn from examination.

Response to Arguments

Applicant's arguments and requests for reconsideration of claim 21 is persuasive because claim 21 is directed to a wrap which is elected, and a paragraph [0091] of the instant application publication states "polymers and polymeric carriers may be fashioned in a variety of forms, such as a film, **wrap**, gel, foam, sheet, mold, **mesh**, coatings and the like. Preferred polymeric carriers may be formed into a film, wrap, gel, foam, sheet, mold, coating or a combination thereof." Secondly, paragraph [0097] also of the application publication states "therapeutic agent and biodegradable polymer are **formed into a mesh or wrap for application** to a venous or arterial anastomosis, preferably on the external portion of the anastomosis." Paragraph [0102] of the application publication describes the mesh materials to be "sufficiently flexible so as to be capable of being wrapped around all or a portion of the external surface of a body passageway or

cavity," and paragraph [0110] teaches a "a device suitable for **wrapping** around a vein or artery includes a **layer of mesh** and a film layer loaded with a therapeutic agent." Therefore, upon further consideration of the election and the wrap of claim 21, and upon consideration that applicant has not indicated that a wrap is distinct from a mesh and the paragraphs of the specification that support that a mesh can be used as a wrap, claim 21 is included with the claims that are examined. The present office action is thus made non-final in view of the consideration of claim 21 that was not examined in the last office action of 9/19/07.

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 2, 13, 14, 21, 26, 27, 34-41, 67-69 and 72 and new claim 232 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (US 5,716,981) in view of Cooper et al. (US 5,962,007) and Datta et al. (US 6,338,739).

4. Hunter discloses an anti-angiogenic composition in the form of a mesh (column 22, lines 51 and 52; column 26, lines 24-26), the mesh comprises anti-angiogenic compound and biodegradable carrier compound (column 3, lines 44-61), which is polyester, polymers and oligomers and copolymers of lactides and glycolides, such a polylactide, polyglycolides and lactide-glycolides or PLGA and blends thereof (column 16, lines 31-56). Example 28 uses paclitaxel as the therapeutic agent (Example 28). The device of claim 1 reads on the composition of Hunter. Hunter's mesh meets the requirements for mesh in claim 1 and since a mesh can either be woven, non-woven or kitted, it would be obvious to have the mesh woven or non-woven or knit so that claim 2 is met. The PLGA of Hunter (column 3, line 58; column 77, lines 54 and 55) reads on the polymer/biodegradable polymer of claims 1, 13, 26, 27. The mesh comprising the carrier and antiangiogenic agent, paclitaxel, meets claims 14 in that the paclitaxel, an ati-proliferative agent is inherently residing within the fibers of the mesh and the paclitaxel meets the requirements of claims 67-69. Example 28 also uses either PCL or PDLLA or PLGA and uses 50:50 PLGA (column 78, lines 21, 55). The composition of Hunter having the therapeutic agent, anti-angiogenic agent or paclitaxel has polymeric carrier, such as PLGA, McPEG-PLGA (column 18, line 35) with the McPEG-PLGA meeting the limitations of claims 26 and 34-37. Claim 72 recites the intended use or properties of the antiproliferative agent in the composition claim 1 and since composition of Hunter contains paclitaxel an anti-proliferative or anti-angiogenic agent, the composition is inherently capable of possessing these properties

and is also capable of performing the intended use. Regarding claims 40 and 41, the artisan has good reason to use MePEG having molecular weight that would produce polymeric carrier desired for the anticipated delivery of the antineoplastic agents. Regarding claim 21, Hunter does not specifically teach that the mesh is rigid and because the mesh of Hunter is not specifically disclosed as being rigid, Hunter's mesh would be capable of being formed into a wrap according to the requirements of claim 21 in the absence of factual evidence. Claim 232 recites the intended use of the composition of claim 1 such that the mesh product of Hunter in view of Copper and Datta would also be capable of being used as a perivascular wrap or used to wrap the blood vessel in the embolization process in the treatment of tumors.

However, the PLGA has 50:50 lactide and glycolide in Example 28 and Hunter does not teach a lactide glycolide ratio of 3:97 to about 15:85, in which the polymer has a higher percent of glycolide. However, Cooper discloses polymeric carrier, polyglycolide –co-lactide polymer having ratios of 95:5 to 5:95 for carrying varieties of different therapeutic agents such an antineoplastic agents (column 4, lines 7-10, 56). Furthermore, it is known in the art that biodegradable polymers such as PLGA, is faster degrading when the polymer is rich in glycolide, such as having at least 80 mole percent as evidence by column 3, lines 50-55; column 4, line 17). Therefore, taking the teachings of the references together, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success to modify the composition of Hunter by optimizing the monomer amounts of the glycolide and lactide to arrive at the anticipated delivery vehicle having the desired biodegradation for the delivery and release of the anti-angiogenic agent/anti-proliferative agent. The composition optimized for the amounts of lactide/glycolide meets the lactide rich polymer requirements of claims 1 and 38, 39.

Therefore, absent a factual showing, percent glycolide rich polymers in the ranges recited is not inventing over the teachings of the prior art.

Response to Arguments

Applicant's arguments filed 1/22/08 as it relates to the current rejections have been fully considered but they are not persuasive.

Applicant argues that Hunter does not teach lactide:glycolide ratio ranging from 3:97 to about 15:85, methoxy-PEG:polyester ratio of about 10:90 to about 30:70 (claim 38) and 20:80 (claim 39). The examiner agrees with the applicant that Hunter does not teach the range in the ration of the monomers and the methoxyPEG:polyester and that is why a rejection under 35 USC 103 is now made and not 35 USC 102. However, those ranges are rendered obvious by the combined teachings of the prior art references according the rejections above.

Claims 1, 26 and 34-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (US 5,716,981) in view of Cooper et al. (US 5,962,007) and Datta et al. (US 6,338,739) and further in view of Zhang et al. ("Development of amphiphilic diblock copolymers as micellar carries of taxol," in International Journal of Pharmaceutics 132:195-206, 1996, pp. 195-206, provided by applicant on 11/27/07 on PTO form 1449).

The teachings of Hunter, Cooper and Datta are described above as rendering claim 1 obvious when the teachings of the references are taken together. While the ordinary skilled artisan has ordinary capabilities of using methoxy PEG having appropriate molecular weight for the methoxy PEG:polyester polymer in ratios appropriate to produce desired delivery carrier polymer, the prior art does not specifically teach the limitations of claims 38-41. But Zhang teaches that the molecular weight of the MePEG and the weight ratio of the PDLLA and MePEG

influence the ability of the polymer in solubilizing taxol (3rd full paragraph of page 126). Therefore, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that taking the teachings of the references together, modification of the polymer in view of the teachings of Zhang would lead to composition that would give the desired solubility of paclitaxel, which is a taxol.

Claims 1 and 232 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (US 5,716,981) in view of Cooper et al. (US 5,962,007) and Datta et al. (US 6,338,739) and further in view of Schrayer (US 6,575,887).

Claim 1 is described above as rendered obvious by the combined teachings of Hunter, Cooper and Datta. Claim 232 recites the intended use of the composition of claim 1 such that the mesh product of Hunter in view of Copper and Datta would also be capable of being used as a perivascular wrap or used to wrap the blood vessel in the embolization process. But, one of the goals of hunter is the embolization of blood vessels in the treatment of tumors using the paclitaxel containing composition (abstract; column 4, lines 14-19). Schrayer teaches wrapping blood vessels to mitigate overexuberant cellular proliferation (abstract; column 1, lines 8-12; column 4, lines 22-36). Therefore, one having ordinary skill in the art the time the invention was made would have reasonable expectation that wrapping the blood vessels in diseased tumor or cancer conditions would successfully mitigate proliferating cellular conditions.

Claims 234 and 235:

Claims 234 and 235 depend from claim 233 and since claim 233 is withdrawn from consideration, these claims, 234 and 235 are also withdrawn form consideration. However, because claims 234 and 235 are directed to paclitaxel, they are also rejectable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618